REMARKS/ARGUMENTS

Claim Rejections - 35 USC § 112 (Claims 9 and 17)

1. The Examiner maintained the rejection of claims 9 and 17. Applicants have amended claims 9 and 17 to render said claims more definite. Such changes add no new matter.

Claim Rejections - 35 USC § 112 (Claim 10)

2. Claim 10 reads:

> 10. (Previously Amended) A formulation according to claim 6, characterized by containing: (a) from 10 to 50% by weight, of at least one active principle with a pharmaceutical, dietary or alimentary action; (b) from 5 to 30% by weight of said fatty acid and (c) excipients and/or adjuvants, the sum of the components (a), (b) and (c) making up 100% by weight of the formulation.

3. The Examiner rejected claim 10 as being indefinite, arguing that the term "vehicle" is a broad and generic one; furthermore, the Examiner is of the opinion that the specification does not define this term in such a way as to exclude standard excipients and adjuvants.

4. Applicants respectfully disagree. The application, at page 3, third paragraph clearly states that:

> ...the active principle or principles, which may be used as such or in the form of esters of physiologically acceptable salts, can be mixed directly with said at least one fat and/or phospholipid without the addition of any excipients and/or adjuvants; in this case, the active principle or principles make up 70-95% by weight, preferably 75-90% by weight of the formulation.

Emphasis added.

5. As such, claim 10 is not indefinite.

Claim Rejections - 35 USC §103

6. Applicants maintain their arguments previously made regarding why the present invention is patentable over Okada *et al.*

7. The Examiner rejected claims 1-17 under §103(a) as being unpatentable (obvious) in view of Okada *et al.*

8. Applicants note that they have amended claim 1 to include the limitations that: (1) the active principle be present in the amounts of between 70 and 95% by weight; and that the active principle be mixed with at least one hydrogenated fatty acid in the melted stated without the addition of any excipients and/or adjuvants. The claimed formulation (claim 1) thus does not contain any excipients and/or adjuvants.

9. These elements are not present in Okada et al. As such, Okada cannot anticipate the present invention.

10. The Examiner argues that the term "vehicle" is a broad and generic one, and mentions that the Examiner "cannot find a portion [of the specification] that defines the term 'vehicle' in such a way as to include only hydrogenated fatty acids and exclude the standard excipients and adjuvants as listed therein."

11. Applicants respectfully disagree. The application, at page 3, third paragraph clearly states that:

> ...the active principle or principles, which may be used as such or in the form of esters of physiologically acceptable salts, can be mixed directly with said at least one fat and/or phospholipid without the addition of any excipients and/or adjuvants; in this case, the active principle or principles make up 70-95% by weight, preferably 75-90% by weight of the formulation.

Emphasis added.

12. The Examiner further argues that "the presence of the additional vehicles, as disclosed in the prior art, would be detrimental to its function."

13. This, however, is not the point. Applicants are not stating that the traditional retarding agents, such as those disclosed by Okada, are detrimental to the invention (in the sense that no retarded release effect would be achieved) because Okada does disclose a sustained-release formulation.

14. The point is that the Applicants have demonstrated that it is possible to obtain a sustained-release effect without the use of traditional retarding agents; and this possibility is not disclosed or even remotely suggested by Okada.

15. Otherwise stated, the purpose of the present invention is that of providing a sustained-release formulation, which is an alternative to that disclosed by Okada, which contains vehicles of biological origin only (i.e., hydrogenated fatty acid), and which does not contain any excipient and/or adjuvant of synthetic origin (such as the hydroxypropylmethylcellulose disclosed by Okada).

16. The Examiner's arguments regarding "the examiner's position that the selection of granulating hole sizes and cooling temperature ranges..." is rendered moot based upon the Applicants' aforementioned amendments to claim 1, in that Okada does not anticipate nor render obvious claim 1-18.

17. Applicants have added new claim 18, which merely works with the amendment to claim 1 (now claims "70-95%") to claim a narrower subembodiment ("75-90%"). Such changes add no new matter.

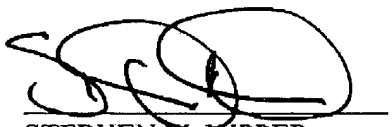
Conclusion

A *prima facie* case of obviousness has not been stated. First, there is no suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, the prior art reference fails to teach or suggest all the claim limitations. For these reasons, the present invention is not obvious in view of Okada *et al.*

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below. Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 4th day of May 2004.

Very respectfully,



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DATE: May 4th, 2004

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